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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,627	04/17/2001	Robert A. Scott	6514-11-BHJ	7296

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EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	**PAPER NUMBER**
1615	14

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/836,627	Applicant(s) COLE ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Applicant's amendment, filed on May 27, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-25 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatano et al. (EP 0754452 A2), in view of Watts (WO 95/35100).

The claimed invention refers to a drug delivery composition consisting essentially of a HPMC capsule provided with a single aqueous coating for delivering a drug in the small intestine or colon.

Hatano et al. discloses a coated capsule containing an acidic substance, a polymer film and an enteric coating, for medicament delivery to any site between the upper part of the small intestine and the lower part of the large intestine in the digestive tract (See p.3, lines 7-10). Hatano et al. explains that the enteric coating film protects the pharmaceutical preparation in the stomach and dissolves in the upper part of the small intestine, allowing the digestive juices to gradually penetrate and dissolve the acidic substance in the hard capsule (See p. 3, lines 11-19). Hatano et al. teaches that the pharmaceutical agents in the capsule can be selectively released at any desired site between the jejunum and the rectum and that any type of capsule can be used in the

invention, including HPMC capsules (See p. 4, lines 6-20). Hatano et al. teaches that the enteric polymer used for the enteric coating film must be soluble in a pH higher than 5 and includes a cellulose derivative, an acrylic polymer, a maleic copolymer, a polyvinyl derivative, shellac and the like among the polymers used for the enteric coating (See p. 4, lines 46-49). Among the exemplary polymers, Hatano et al. includes HPMCP, methyl acrylate-acrylic acid copolymer, methyl acrylate-methacrylic acid copolymer and PVAP (See p. 4, lines 50-58 and p. 5, lines 1-9). The examiner, for the purpose of the invention, considers cellulose ester, which is mentioned in claim 15 of the present application as a component of the coating, as a cellulose derivative. Hatano et al. teaches that the amount of the enteric coating film is from 10 to 400% by weight based on the weight of the hard capsule (See p. 5, lines 41-46), and that the medicament in the capsule is not limited as long as it is orally administrable (See p. 8, lines 3-9). Hatano et al. teaches that preferable solvents for the coating solution are water and alcohol (See p. 9, lines 8-19). Additionally, Hatano et al. teaches that a sealing means can be provided around a joint of a body and a cap of the hard capsule and explains that the sealing agent can be any substance able to make the capsule's surface smooth at the joint, such as a water-soluble or insoluble polymer, a low pH-soluble or enteric polymer, a saccharide or the like (See p. 9, lines 23-55).

Thus, Hatano et al. provides a HPMC capsule provided with an enteric coating for delivering a drug in the small intestine or colon. Even though Hatano et al. contemplates a capsule coated with multiple coatings, the reference teaches that only one enteric coating, which is soluble in an aqueous medium at pH higher than 5, is applied to the capsule. Hatano et al. is deficient in not including a redox sensitive material in the coating of the HPMC capsule.

Watts discloses a drug delivery composition for delivering a drug to the colonic region, comprising a coated starch capsule containing the drug (See p.3, lines 25-29). Watts teaches that the coating may be pH-sensitive, redox-sensitive or sensitive to particular enzymes or bacteria, so that the capsules do not release the drug until it is in the colon (See p. 5, lines 9-14). Watts teaches that preferred coating materials are those which dissolve at a pH of 5 or above, including CAT, HPMCP, PVAP, shellac and cellulose esters, and that especially preferred materials are methylmethacrylates or copolymers of methacrylic acid and methylmethacrylate (See p. 5, lines 20-30 and p. 6, lines 1-22). Watts explains that, because of the high presence of microbial anaerobic organisms providing reducing conditions in the colonic region, the coating may comprise a redox-sensitive material, such as azopolymers, which are broken down enzymatically, or disulphide polymers (See p. 6, lines 24-30 and p. 7, lines 1-2).
It is the view of the examiner that one of ordinary skill in the art would determine the optimal amount of the coating according to the size of the capsule by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery system disclosed by Hatano et al., by including a redox sensitive material in the coating of the HPMC capsule, as taught by Watts, and applying the suitable coating in the optimal range determined by routine experimentation, before or after filling the capsule with the caplet, to ensure a complete disintegration of the coating in the small intestine or the colon and prevent drug leaking in the stomach.. The expected result would have been a successful drug delivery composition. Because of the teachings of Hatano et al., that any kind of medicament can be delivered to any desired site between the upper part of the small

intestine and the lower part of the large intestine in the digestive tract, by controlling the amount and the kind of polymers used for the coating of the HPMC capsule, one of ordinary skill in the art would have a reasonable expectation that the HPMC capsule device of the present application would successfully deliver drugs to the small intestine or colon. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

3. Applicant's arguments filed on May 27, 2003 have been fully considered but they are not persuasive.

4. Applicant argues that none of the prior art teaches a HPMC coating consisting essentially of a single coating. In response to said argument, it is noted that Applicant's invention reads on a drug delivery composition consisting essentially of a HPMC capsule provided with a single aqueous coating, and not on a HPMC coating consisting essentially of a single coating, as argued by Applicant. The single aqueous coating claimed by Applicant does not exclude the presence of additional coatings, as in fact claim 22, which depends on claim 1 of the instant application, reads on a composition, wherein the HPMC capsule body is coated with an insoluble polymer and the cap is enteric or colonic coated. Thus, in Applicant's invention the HPMC capsule body is coated with an insoluble polymer and a single aqueous coating. Hatano et al. contemplates a single aqueous coating, as the reference teaches that the enteric polymer, which is a polymer soluble in an aqueous medium at pH higher than 5, may be used alone (See p. 4, line 46 to p. 5, line 11).

5. In response to Applicant's argument, that Watts discloses capsules having multiple coatings, it is noted that Applicant's invention reads on a drug delivery composition consisting essentially of a HPMC capsule provided with a single aqueous coating, and not on a HPMC coating consisting essentially of a single coating, as argued by Applicant. The single aqueous coating claimed by Applicant does not exclude the presence of additional coatings.

Conclusion

6. Claims 1-25 and 29-33 stand rejected.

7. Applicant's amendment has overcome the objection to the specification of the previous Office action. Accordingly, said objection is withdrawn.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDNB3

June 24, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600